

Remarks/Arguments:

This Response adds no new claims, and does not amend any claims. Upon entry of this Response, claims 1-13 will be pending. Claims 1 and 7 are independent.

Please note that a Response and Amendment in regard to an unrelated application entitled "Secure Speech", of Mastrianni et al., has been mistakenly entered in the file of the present application through no fault of the Applicants. This Response and Amendment in regard to the unrelated application entitled "Secure Speech", of Mastrianni et al., does not relate to the present application, nor to the present Applicants. The present Applicants have notified the Examiner of the present Application, Nancy Bitar, and have notified the Applicant of the unrelated application, of this mistaken entry.

Rejections of the Claims under 35 U.S.C. 103

The Examiner has rejected claims 1-13 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent Publication No. 2005/0019945 of Groll et al. (hereinafter Groll) in view of U.S. Patent No. 6,765,555 of Wu et al. (hereinafter Wu).

Specifically, regarding claims 1 and 7, the Examiner points to Groll as describing the claimed invention with the exception of an optical sensor with an imaging array of pixels. That is, the Examiner points to Groll as disclosing a test strip reader having an optical sensor, a light source, a channel configured for receiving a test strip to be imaged by the test strip reader and for guiding the insertion and removal of the test strip with respect to the optical sensor, the test strip comprising optically detected information, a lens positioned with respect to the imaging array and the light source to focus light from the light source that has been reflected from the test strip onto the imaging array, the optical sensor being operable to determine change of direction data corresponding to the position of the test strip with respect to the optical sensor and a processing device connected to the optical sensor for using the change of direction data to determine the position of the test strip with respect to the test strip reader, and for determining at least one of the optical absorptions of the information on the test strip, and diagnostic significance of the information on the test strip. The Examiner points to Wu as describing a sensor array that includes a plurality of individual pixels

arranged in a two-dimensional array, purportedly rendering obvious the invention as claimed by the Applicants in claim 1, and a reading method thereof as claimed by the Applicants in claim 7.

The Groll reference describes a system and method for the construction of an electromechanical test strip, which is etched to have a number of electrical traces and connections, including encoded electrical connections for identifying the inserted strip, for use with an electric circuit of a reader when electrical connectivity is established via a number of contact pads (see Figs 2-3, and paragraph 71 (discussing prior art requiring manual id input by a user) and paragraphs 74-75 in regard to the system and method of Groll).

In regard to the optical sensor as recited by the Applicants, the Examiner points to the biosensor 401, and the manufacturing of the biosensor 401, of the Groll reference (see paragraph 58).

The biosensor 401 of Groll is simply an electromechanical test strip, which is etched to have a number of electrical traces and connections, including encoded electrical connections for identifying the inserted strip, for use with an electric circuit of a reader when electrical connectivity is established via a number of contact pads. The biosensor 401 does not comprise nor suggest any optical capabilities, either to optically read data or to optically communicate data. That is, all sensor information of the biosensor 401 is communicated via electrical contacts only.

In regard to paragraph 58 of Groll, this simply describes an ablation apparatus 410 for the manufacture of the biosensor 401 using masking/etching techniques. The components of the ablation apparatus 410, as described in greater detail below, are not components of either the biosensor 401 or a reader device (not shown in Groll) for the biosensor. Still further, the sole optical capability of the ablation apparatus 410 if having any at all, is limited to the emission of a laser light for etching of the mask pattern upon the substrate material 420, which does not provide any optical sensing functions. That is, the ablation apparatus also does not describe or suggest an optical sensor of a test strip reader as recited by the Applicants.

Further, where the etching by the ablation apparatus 410 is considered optical communication with the biosensor 401, the Applicants assert that the ablation apparatus provides the laser to a component only of the biosensor prior to completion and assembly, and not to the complete biosensor (see Groll Fig. 1). That is, the ablation apparatus operates upon a substrate, which is not the biosensor apparatus but simply a component. Accordingly, the fabrication steps of a component would not render the completed and assembled biosensor 401 an optical sensor. For example, any optical sensor abilities, derived from the assembly process, would be effectively ended by the assembly of the covers 16 and 18.

In the Examiner's response to Applicants' previous arguments, the Examiner points out that the ablation apparatus 410 includes a laser source 411, laser 412, mask 414 and optics 416. However, these elements are in regard to the system and method for the manufacture of the biosensor 401 (see Fig. 4). They are not part of the biosensor 401 or a reader device for the biosensor. Further, as noted above, their use to construct the biosensor 401 does not make the biosensor an optical sensor. The biosensor itself is clearly an electromechanical sensor and is described as such (see paragraph 44), and does not describe or suggest an optical sensor as recited by the Applicants.

The Examiner further states that Groll describes non-contact data retrieval from the biosensor 401 at paragraph 51. The Applicants assert that the non-contact system and method of paragraph 51 is in regard to determining, in other ways, connectivity between pads DC, B1, B2 and C as alternate methods to determine the eight possible numbers encoded on the test strip. That is, paragraph 51 first describes evaluating resistance between each (see line 12), then states determining...“other than by measurement of resistance...” (see line 18). The term resistance and its alternate methods are clearly in regard to connectivity between pads, and not in regard to communication between the biosensor and a reader device. Further, lines 15-18 of paragraph 51 state that the other methods are used to determine conductive links on the strip, and not in regard to communication between the biosensor and a reader device. Accordingly, the Applicants assert that Groll does not describe or suggest any non-contact use of the biosensor 401, and that the biosensor or the ablation apparatus 410, alone or in combination, do not describe or suggest an optical sensor as recited by the

Applicants in independent claim 1, or a reading method thereof as recited by the Applicants in independent claim 7.

The Examiner points to the laser light 412 of the manufacturing ablation apparatus 410 as describing the light source as recited by the Applicants in independent claim 1. However, as noted above, the ablation apparatus 410 is provided for constructing a component of the biosensor 401. Specifically, it is used during construction of the substrate including its many electrical traces and contacts. That is, the laser light 412 of the Groll reference is used to etch/fabricate the substrate as exposed by the masking. The biosensor is then assembled and covered by the spacers 16 and the top foil layer 18 for use (see Fig. 1). Accordingly, the laser 411 and laser light 412 are used in construction of the circuit elements only, and would have no use with the assembled biosensor given the covers 16 and 18. That is, the laser 411 and laser light 412 are used in manufacturing a component of the biosensor, and are not part of a test strip or test strip reader into which the biosensor 401 would be placed.

In the Examiner's response to Applicants' previous arguments, the Examiner points out that the laser and mask are part of the ablation apparatus 410. The ablation apparatus is used with a component of the biosensor only, and is not used with an assembled biosensor. As such, the laser and mask do not describe or suggest components for use with an assembled test strip. That is, the laser and mask do not describe or suggest a light source as part of a test strip reader for use with a test strip or a reading method thereof as recited by the Applicants in independent claims 1 and 7.

Further, the Examiner points to the steps 100 and 110 as describing a channel configured to receive and guide the test strip as recited by the Applicants in claim 1. However, steps 100 and 110, and Groll Fig. 8, simply describe the insertion and withdrawal of a strip. There is no description of the configuration of the apparatus of the reading device with which the steps are performed other than a device in which the test strip is inserted to make contact. Specifically, there is no description of a channel, or a channel for receiving

and guiding a test strip, as recited by the Applicants in claim 1, or a reading method thereof as recited by the Applicants in claim 7.

Still further, the Examiner points to Groll paragraph 82 as describing a test strip comprising optically detected information as recited by the Applicants in claim 1. However, the system and method of Groll is limited to communication via electrical contact between a biosensor and reader only. As noted above, the biosensor 401 of Groll is simply an electromechanical test strip, which is etched to have a number of electrical traces and connections, including encoded electrical connections for identifying the inserted strip, for use with an electric circuit of a reader when electrical connectivity is established via a number of contact pads. The biosensor 401 does not comprise nor suggest any optical capabilities, either to optically read data or to optically communicate data. That is, all sensor information of the biosensor 401 is communicated via electrical contacts only.

Paragraph 82 of Groll simply describes a feature of Groll in which contact trace and connection information of the biosensor when inserted can be used to indicate that a function of the reader should be turned on/off. There is a list of such features that can be activated by such electrical contact between biosensor and reader (see Groll paragraphs 21, 22, 23, 24 and 25, especially step (c) described in each paragraph). Further, the biosensor 401 is described as encoding data using electrical contacts only (that is, electrically detected information only). There is no description in Groll of optically encoded data on the biosensor 401. The use of lasers with the biosensor 401 is limited to fabrication of the contact elements only in the ablation process during fabrication. Once assembled as the biosensor, no optical communication abilities exist. Accordingly, the system and method of Groll does not include any description of optical communication or a test strip comprising optically detected information as recited by the Applicants in claim 1, or a reading method thereof as recited by the Applicants in claim 7.

Still further, the Examiner points to the ablation apparatus 410 of Groll as describing a lens positioned to focus light reflected from the test strip on the imaging array as recited by

the Applicants in claim 1. However, the Examiner notes that it is the *mask pattern* in the ablation apparatus of Groll that reflects some of the light, in contrast to the reflection of light from the test strip as recited by the Applicants (see again paragraph 44 and 68).

Further, the single lens 416 of the ablation apparatus 410 of Groll is provided to shape the laser 412 light onto the substrate of the biosensor 401 for fabrication, and is not described as serving any function in regard to any light reflected back, even if there were any light reflected back by the substrate of the biosensor 401. Further, the lens 416 is positioned after the mask 414, so any light reflected by the mask would not even return through the lens 416 (see Figs. 5 and 6). Still further, the lens is an element of the ablation apparatus and does not describe or suggest a lens that would be found in the test strip reader that would function with an assembled biosensor.

Even further, the Applicants recite a lens positioned to focus light reflected from the test strip onto the optical sensor. In the discussion of the optical sensor above, the Examiner points to the biosensor 401 as disclosing the optical sensor. Accordingly, it is unclear how the lens of the Ablation apparatus could focus light reflected from the mask, which would return toward the laser 411, onto the substrate of the biosensor. That is, the lens 416 focuses direct light upon the biosensor, and does not even receive light reflected by the mask.

Accordingly, there is no description of a lens of a test strip reader to focus light reflected back from the substrate or mask, and more specifically, there is no description of a lens of a test strip reader positioned to focus light reflected from the test strip (or the substrate or mask of Groll) on the optical sensor as recited by the Applicants in claim 1, or a reading method thereof as recited by the Applicants in claim 7.

Still further, the Groll reference does not describe an optical sensor operable to determine a change of direction data as recited by the Applicants. The Examiner first points to paragraph 61 which again describes the ablation apparatus of Groll, but is not part of the biosensor 401 nor of any reader device for use with the biosensor 401. That is, the elements of the ablation apparatus cannot function as part of a biosensor or reader device, and do not

describe or suggest an optical sensor of any sort. It is also unclear how the ablation apparatus 410 is operable to determine a change of direction data.

Where the substrate receiving the laser etching is considered the optical sensor, it is also unclear how the substrate determines a change of direction data. Further, the Examiner points to paragraph 86 which describes a test meter which receives the electromechanical test strip, which is etched to have a number of electrical traces and connections for use with an electric circuit of a reader when electrical connectivity is established via a number of contact pads. However, the test meter also does not describe or suggest an optical sensor operable to determine a change of direction data.

The Examiner notes that the positioning of the mask of the Ablation apparatus, and movement of the substrate component of the biosensor, are computer controlled, and that such control describes an optical sensor operable to determine a change of direction data as recited by the Applicants. The Applicants first note such computer control is not defined nor shown in any detail. However, even where such ablation control is present, it is the direction data of the movement of the test strip with respect to the optical sensor that is recited by the Applicants. As shown in Groll Fig. 5, the ablation control is in regard to the movement of the substrate roll only, and not of a completed biosensor. Still further, there is no description or suggestion of the operation of an ablation controller in regard to a reverse direction of the substrate roll.

Still further, Groll does not describe a processing device connected to the optical sensor for using change of direction data to determine a position of the test strip with respect to the test strip reader. As noted above, Groll does not describe an optical sensor, nor an optical sensor being operable to determine change of direction data (neither the ablation apparatus, the biosensor substrate or the computer control of the ablation apparatus). Accordingly, Groll does not describe a processing device connected to such an optical sensor. Further, there is no description or suggestion of a system or method for detecting a change of direction, or using change of direction data as recited by the Applicants. The Examiner points to contact pads of the biosensor, and paragraph 86 as disclosing such a processing

device. However, there is no description or suggestion of the test meter of the Groll reference as determining change of direction data, or using change of direction data, as recited by the Applicants.

Accordingly, the Groll reference does not describe an optical sensor operable to determine a change of direction data, nor a processing device connected to the optical sensor for using the change of direction data to determine a position of the test strip with respect to the test strip reader. Still further, there is no description of a processing device connected to the optical sensor for determining optically encoded information on the test strip as recited by the Applicants in claim 1, or a reading method thereof as recited by the Applicants in claim 7.

The Examiner points to Wu as describing a passive optical mouse including a sensor array having a plurality of individual pixels arranged in a two-dimensional array, thereby disclosing a an optical sensor with an imaging array of pixels as recited by the Applicants in claim 1, and a reading method thereof as recited by the Applicants in claim 7.

The Wu reference describes an ambient light, optical mouse 201, having a housing 203 and a lens 205. However, the Wu reference does not disclose the additional elements recited by the Applicants which are not disclosed or suggested by the Groll reference as noted above. That is, neither the Groll nor Wu references, alone or in combination, describe each element of Applicants' claim 1 or claim 7. More specifically, as described above, neither the Groll nor Wu references, alone or in combination, describe an optical sensor, light source, channel, lens and processing device as recited by the Applicants in claim 1, and a reading method of use thereof as recited by the Applicants in claim 7.

Accordingly, as the Groll and Wu references do not describe or reasonably suggest each element of Applicants independent claims 1 and 7, the Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. 103(a) of independent claims 1 and 7.

Regarding the remaining dependent claims 2-6 and 8-13, the Applicants assert that the Groll and Wu references do not disclose or reasonably suggest each element as claimed by

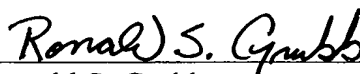
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the Applicants in independent claims 1 and 7, from which claims 2-6 and 8-13 depend. Accordingly, the Applicants respectfully request the withdrawal of the rejection under 35 U.S.C. 103(a) of the remaining dependent claims 2-6 and 8-13 for the same reasons.

Conclusion

In view of the above, it is believed that the application is in condition for allowance and notice to this effect is respectfully requested. Should the Examiner have any questions, the Examiner is invited to contact the undersigned attorney at the telephone number indicated below.

Respectfully submitted,



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